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May 3, 2005

Marc G. Cloutier, Ph.D.
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Dear Dr. Cloutier:

I am writing to provide the third of three reports from the *Committee to Review Proposals to the 2005 Biomedical Wright Centers of Innovation and the Biomedical Research and Technology Transfer (BRTT) Partnership Awards Program of the State of Ohio*. This letter contains a supplementary assessment of a proposal to create the Atrial Fibrillation Innovation Center (AFIC). The proposal, which was submitted to Ohio's Wright Centers of Innovation (WCI) competition, was identified in the committee's first report as having sufficient merit for consideration for funding by Ohio's Department of Development, which administers the WCI program. This assessment is based on the findings of a delegation that recently met with management and scientific team members representing the proposed Center. The report reflects the consensus of the full committee and is intended to provide the Department with guidance in its decision-making process.

Short biographies of the committee membership are enclosed as Appendix A. Details of the committee's expertise, its charge, the review process, and the evaluation criteria used by the committee in its review of proposals to the WCI program are contained in the first report.

The management review meeting took place on April 8, 2005, at the Cleveland Clinic Inter-continental Suite Hotel in Cleveland, Ohio. A team associated with the proposed AFIC met with a delegation representing the review committee. The delegation consisted of committee members Dr. Greg Lanza, Dr. Robert Fischell, Dr. Curtis Jamison and the committee's staff director, Ms. Ann Reid.

The management review explored details of the applicants' plans for the organization and administration of the proposed Atrial Fibrillation Innovation Center (AFIC). Representatives of the scientific and commercialization leadership teams made presentations describing the research plans and development goals for this project. The delegation had ample opportunity to ask questions of the whole group and to meet individually with leaders of specific research areas to ask more in-depth questions.

The delegation communicated its findings from the review meeting to the full committee, which reached consensus on the merits of the proposal and on the following advice to the Ohio Department of Development.

The Atrial Fibrillation Innovation Center (AFIC) represents a collaborative arrangement between the Cleveland Clinic Foundation, Case Western Reserve University, the University of Cincinnati and several private companies including AtriCure, Inc., Biocontrol Medical Ltd., Cyberonics, Inc., Hansen Medical, Philips Medical Systems, Sinus Rhythm Technologies, Inc. (SRTI), St. Jude Medical, Symphony Medical, Boston Scientific and CardioNet, Inc. Of the commercial partners, AtriCure, Symphony, SRTI and Philips either have operations in Ohio or will move operations there if the project is funded.

The group has requested approximately $15.5 million in capital funds and $8 million in operating funds over 3 years. Most of the capital funds ($11.5 million) will be used to build and equip a 16,000 square foot dedicated facility to house the AFIC. The group has also requested $7,995,923 in operating funds, the majority of which is requested for personnel costs.

Scientific Overview:

The committee felt that the effort to engage in an all-out assault on atrial fibrillation is an outstanding choice of direction for the Cleveland Clinic. This is an increasingly prevalent disease of the aging, which was once poorly managed with medicine and now more successfully addressed with surgical or interventional approaches. Today, the best treatment for atrial fibrillation involves electrical isolation of the pulmonary veins from the rest of the atrial tissue.

The AFIC project approaches the problem using both surgical and interventional approaches. Tools to improve surgical ablation of atrial fibrillation are already in development by Atricure and gaining market share. However, important tools, such as the real-time application of cardiac electrical mapping, which would effectively localize specifically which tissue to isolate and which could help determine when atrial foci had been segregated, is not a real-time procedure in the OR. AFIC surgical projects will try to adapt real-time electrocardiomapping to the OR environment, to improve tools available to create precise atrial lesions, and to develop techniques to perform the operation using minimally invasive techniques (as opposed to open chest surgery).

From the interventional perspective, many sites are exploring a wide variety of techniques to create atrial tissue lesions from within the left atrial chamber. These approaches involve transeptal interventions, which provide access to each of the four pulmonary veins and the left atrial appendage. However, once within the left atrium, manipulation of catheters to the oblique location of pulmonary veins can be difficult, time-consuming, and physically taxing to the operator. The committee was impressed that the Cleveland Clinic is a leader in this area, having, for example, reduced the amount of time required for catheter-based intervention from the typical eight hours to only three.

The AFIC investigators will attempt to utilize and superimpose CT images with the guidance platform to provide direct catheter tip localization within an internal 3D view of the left atrium. From this perspective assured placement of the catheters is expected to lead to greater efficacy with reduced complications. With further effort, they propose to integrate real-time color depictions of electrical activation onto the 3D CT image surface. This could provide the optimal, nonsurgical visualization approach. Finally the AFIC interventionalists are proposing to develop novel ablation catheters, which will utilize cryotherapy on pulmonary vein tissue with purportedly reduced formation of thromboses, which is common with radiofrequency energy.

It is clear that atrial fibrillation is not a uniform condition but rather represents a collection of diseases that are likely to have different causes, prognoses and responses to treatment. Therefore, in addition to surgical and interventionist approaches to treating AF, a third component of the AFIC program is an examination of the variables characterizing the patient's disease, genotype and physiological status, their medical history and response to treatment.

A variety of basic science projects will attempt to identify genetic, transcriptional and immunohistochemical markers associated with atrial fibrillation. The chances for success of these basic science programs are greatly enhanced by their integration with the rest of the AFIC program and it is possible that the investment of the State of Ohio in these projects will allow them to attract more federal research funding.

A second component of the AFIC's efforts to better characterize AF involves using a mixed model approach and computer processing power to blend data collected throughout the AFIC project into a set of guidelines, which could help establish individualized ablation treatment strategies. The computational and bioinformatics portion of the work was poorly described in the original proposal. The presentation by Dr. Blackstone and subsequent discussions during the site visit reassured the committee that the team has adequate expertise and resources to tackle this very challenging task of information collection, organization and analysis. These techniques may eventually be used to predict and avert the progression toward atrial fibrillation and provide a basis for new and better medical therapy. In the short term, one can envision this component of the project developing diagnostic characterization kits, which could be used to evaluate patients exhibiting the disease or with a propensity for the problem. In the longer term, this component of the project could also represent the development in Ohio of valuable expertise in large-scale, multi-factorial database design and data mining that could be useful across medical disciplines.

Finally, the AFIC program includes a "novel technologies" component, involving high intensity ultrasound and neurological intervention, which are reasonably established technologies now being applied to atrial fibrillation. The committee was encouraged by information gained during the meeting that the neurological approach will not rely on continuous or automatic stimulation of the vagus nerve but instead will be triggered in response to an atrial fibrillation signal from the heart. These approaches may produce new applications that could reach the marketplace rapidly given the wealth of prior experience in the industries that exist around them.

In short, the committee was extremely impressed with the breadth and depth of the scientific resources and the diversity of approaches that will be brought to bear on this important and complicated disease. The committee is confident that this group will be able to make significant contributions to the treatment of atrial fibrillation and that the project is very likely to result in substantial economic development. This confidence sustained the committee's enthusiasm for the project in the face of some serious concerns about accountability and budget issues.

Accountability issues:

The committee was concerned that some projects within the AFIC program are still at the speculative, discovery stage and are unlikely to result in commercializable products even in the medium term. For example, the basic science program is at such an early stage that, standing alone, it would probably not be appropriate for funding under the BRTT or WCI programs. The basic science component in the AFIC plan is a high-risk but possibly very high-gain activity. The unusually large group of patients these researchers will have to work with and the resources devoted to information management and analysis increase the likelihood that the researchers will identify genetic markers for different types of atrial fibrillation. Therefore, it seems appropriate to retain these programs. However, the milestones presented for the basic science projects are wholly inadequate, providing no more detail than "we're going to work hard on this for 3 years and see what happens." The committee strongly encourages Ohio to require much more detailed plans from this team. In particular, the resources anticipated for the genetic characterization of AF (5% effort by Dr. Wang to supervise a newly hired post-doctoral fellow and technician) do not seem likely to result in significant progress on this front within the three-year time-frame of WCI funding. More detailed plans and proposed milestones would allow the State and AFIC leadership to assess whether the resources currently projected are adequate.

Although the committee had confidence that the expertise and resources devoted to the "assessment and analysis of outcomes development" project are adequate, again, meaningful milestones have not been provided. Similarly, several of these projects listed under "new technology development" (fibroblasts and fibrin sealants development, application of high intensity ultrasound development, novel implantable devices development and selective vagal nerve stimulation) have not provided specific and measurable milestones.

The strength of this proposal is felt to be in the assembly of diverse teams working on the same problem. The hope is that the diversity will lead to novel insights and new research directions. The committee strongly recommends that a more detailed plan be developed and submitted to the state before any funds are provided and the clock started, but that the assessment process leave room for changes of emphasis as projects unfold. Should this proposal be funded the committee suggests that each component project of the entire AFIC program be required to provide acceptable milestones and deliverables on a yearly basis. Moreover, a critical path graphic of these milestones, their interrelationships and the basis and timing for "go-no-go" decisions for development should be developed. Without such documentation, it will be difficult to assess the progress of this program over time. Care should be taken, however, to leave room in the assessment process for currently unforeseeable developments and discoveries.

Budget Issues:

The committee expressed serious concern about the lack of appropriate levels of cost-sharing for requested capital funds. The Wright Centers of Innovation request for proposals (RFP) specifies that all proposal budgets must demonstrate that they have obtained cost share with an auditable monetary value of at least two (2) dollars for every one (1) dollar of capital funds awarded. The three-year budget plan for the center does not show expected sources of cash and in-kind contributions that meet this requirement; only $17,407,069 in cost share is shown for WCI capital funds request of $15,532,477. Substantial cost-share by participating institutions, totaling $27.2M, is promised for the approximately $8M in requested operating funds. Thus the three-year budget plan for operating expenses substantially exceeds the required 1:1 match. In response to questions about the lack of adequate matching funds for the capital request, the applicants pointed out that overall cost-share commitments of $51M exceed the $39M match that would be required under a strict 2:1 match for requested capital funds ($31M for $15.5M requested) and a 1:1 match for operating funds ($8M for $8M requested). The applicants seem to be contending that the cost-share is adequate in spirit, but the State of Ohio should note that the proposed cost-share is not compliant with the RFP.

Furthermore, the source and nature of some of the cost-share contributions are unclear, somewhat diminishing the credence of the cost-share totals. Contributions from BioControl Medical, Biosense Webster, CardioNet, Prognostix, SRTI, Cyberonics and Hansen, for example, appear either to be in the form of services provided at reduced rates or the precise form of the promised cost-share is unspecified. In general, the letters of support are vague and general, and in many cases begin with identical language suggesting that they were prepared centrally for each participant's signature. The committee recommends that the State of Ohio require each partner to submit a detailed letter explaining the services, products, equipment or technologies they will provide to the project, the payments they expect to receive and from whom, and the source, nature and timing of cost-share that they will provide. It is not clear whether payments to these companies for services and tests will be in the form of subawards from the Cleveland Clinic Foundation (CCF) from WCI funds. Subawards of $6.3M are listed on the CCF "Source and Use of Funds Table" but the CCF Budget Detail states that no funds are requested for subawards. If WCI funds for these companies are to be channeled through the Cleveland Clinic Foundation, this fact should be made more transparent.

Finally, it is clear that significant private resources are already mobilized to invest in the AFIC concept. The committee was impressed with the array of commercialization expertise and venture capital that appears poised to shepherd any promising technologies that might emerge from AFIC and no concerns were raised about the organizational or management structure. The topic, then, of whether the investment of state funds is truly necessary, needs to be broached. The AFIC representatives were asked directly what the state funds would make possible that could not be achieved through private funding. Fundamentally, the answer appears to be that while individual components of the AFIC program would doubtless be able to proceed with private funding, an integrated, multi-faceted attack on the disease in a single facility could not be achieved without public investment. In particular, raising funds for a new facility to house the effort would not be

possible. While difficult to quantify, the members of the AFIC team are convinced that physical proximity of the different researchers will lend a synergy to the overall program that would be missing if the projects were to proceed independently. The committee members were inclined to agree with this assessment, knowing from experience that chance hallway conversations can be far more productive than even frequent board and committee meetings. Nevertheless, the AFIC is asking the WCI program to fund a greater proportion of these capital costs than is envisaged in the WCI RFP and the state should consider carefully whether the private partners have contributed sufficiently to this vision.

In summary, the committee is extremely optimistic about the scientific and commercial potential of the Atrial Fibrillation Innovation Center. However, it is concerned that many of the component projects have not provided enough information for the state to be able to monitor progress. Critically, it is also very concerned that the institutions that are poised to benefit the most from the creation of such a center are not providing adequate matching funds. The committee, therefore, recommends that Ohio address the issues of cost-sharing and accountability before proceeding with this very promising Center.

Sincerely,

Barbara Hansen
Chairman
Committee to Review Biomedical Proposals to the 2005 Wright Centers of Innovation and the Biomedical Research and Technology Transfer Partnership Awards of the State of Ohio

cc: Warren Muir
Frances Sharples
Ann Reid

Appendix: Committee Biosketches

Marc G. Cloutier, PhD
May 3, 2005

APPENDIX

Committee on Review of Biomedical Proposals to the 2005 Wright Centers of Innovation & the Biomedical Research & Technology Transfer Partnership Awards of the State of Ohio

Committee Biosketches

Barbara C. Hansen, Ph.D., Chairperson
A leading authority and lecturer in the relationships between overweight and diabetes, Barbara Hansen is a professor of physiology at the University of Maryland School of Medicine and Director of the University's Obesity and Diabetes Research Center, the Obesity, Diabetes and Aging and Animal Resource and the Director of Research, Joslin Clinic. Science policy issues of interest include animal care and use, scientific ethics (including misconduct, fraud, data ownership issues), and indirect costs. Dr. Hansen is a member of the Institute of Medicine of the National Academies. She has served as an advisor and consultant to many other leading scientific societies and organizations, including the National Institute of Health, the Robert Wood Foundation, and the National Institute for Environmental Health Sciences. She holds B.S. (summa cum laude, valedictorian) and M.S. degrees from the University of California at Los Angeles and a Ph.D. in physiology and psychology from the University of Washington.

Frederick A. Lenz, M.D. Ph.D.
Dr. Lenz is Professor of Neurosurgery at Johns Hopkins University and Chief of the Epilepsy Surgery at the Johns Hopkins Hospital. He received an MD and PhD from the University of Toronto, and is a Fellow of the Royal College of Surgeons, Canada. Dr. Lenz serves on several NINDS study sections and has published numerous articles on the subjects of his research, including the biology of human cortical pain-related activity and neurosurgical procedures for treating neuropathic pain. He is the recipient of several honors, including the MacKenzie Award of the Royal College of Surgeons of Canada and World Neurosurgical Society, and the Elsberg Award of the New York Academy of Medicine.

Curtis Jamison, Ph.D.
Dr. Jamison is currently Associate Professor in the Department of Computational Biology at George Mason University. His research interests include gene expression analysis and analysis infrastructure; Laboratory automation interface for capturing laboratory workflow into databases; Data representation and visualization, specifically pertaining to comparative genome mapping and correlation of genetic, RH, and genome maps; and Database federation and cross-referencing. He recently served on a committee to review the progress of the first (2001) Ohio BRTT grantees.

Peter Adamson, M.D.
Dr. Adamson is chief of the Division of Clinical Pharmacology and Therapeutics at the Children's Hospital of Philadelphia. He received his BA from Wesleyan Universify and his MD in 1984 from Cornell University Medical College. After a pediatrics residency at the Children's Hospital of Philadelphia, he spent 12 years at the National Cancer Institute before returnng to the Children's Hospital of Philadelphia. He also holds an appointment

as Associate Professor of Pharmacology at the University of Pennsylvania School of Medicine. His expertise is in the development of drugs for the treatment of pediatric cancers and he served on the Institute of Medicine's National Cancer Policy Board Committee: "Shortening The Time Line For New Cancer Treatments" (2001-)

Gail Naughton, Ph.D.
Gail Naughton is the Dean of the School of Business at San Diego State University. She was a co-founder of the La Jolla-based Advanced Tissue Sciences and later served as vice chairman of its board of directors. Dr. Naughton was awarded the Intellectual Property Owner's Association's National Inventor of the Year Award in 2000 for her work in tissue engineering. Dean Naughton has served on the advisory board or the SDSU College of Business Administration's Entrepreneurial Management Center since 1997. She also sits on the advisory boards of the Department of Bioengineering at John Hopkins University and the Georgia Institute of Technology, and she is a member of the Industrial Liaison Board at the University of California, San Diego, the Georgia Institute of Technology, the Massachusetts Institute of Technology, and the University of Washington. In addition, Dr. Naughton is a member of the board of directors of the Stern foundations, the Ackerman Foundation and the scientific advisory board of Frantz Medical Ventures. She received her Ph.D. in basic medical sciences from New York University in 1981. She earned her executive MBA from UCLA in 2001.

Russell Dills, Ph.D.
Dr. Dills is Director of the Environmental Health Laboratories and Trace Organics Analytical Center in the Department of Environmental Health at the University of Washington, Seattle. His research focuses primarily on the development of methods for human dosimetery of organic chemicals. Dr. Dills' research emphasizes biomarkers of exposure, with studies ongoing of organic constitutes of particular matter (polynuclear hydrocarbons and wood smoke chemicals), toxicokinetics of solvent exposure, components of dental composites, and mold related toxins. Prior to his appointment at the University of Washington, he worked in the Department of Pharmacology, Toxicology and Experimental Therapeutics at the University of Kansas Medical Center. Dr. Dills received his Ph.D. from the University of Kansas in 1986.

Gregory Lanza, Ph.D., M.D.
Gregory M. Lanza is currently Associate Professor of Medicine and Bioengineering at Washington University School of Medicine. His research interests include noninvasive molecular imaging and drug delivery research, i.e., tissue specific imaging and therapy. Dr. Lanza has developed and patented a novel, ligand-targeted, lipid-encapsulated, nongaseous perfluorocarbon emulsion for use with ultrasound, magnetic resonance and nuclear imaging modalities. This multidimensional platform technology also facilitates targeted drug delivery. Coupling molecular imaging with therapy allows quantification of drug delivered to a specific site. Current areas of molecular imaging and targeted drug delivery research include: 1) thrombosis and vulnerable atherosclerotic plaques, 2) arterial restenosis following angioplasty, 3) angiogenesis for solid tumor, atherosclerosis and wound healing , and 4) early detection of atherosclerosis, organ rejection and other inflammatory diseases

Alexander R. Margulis, M.D.

Dr. Margulis was chairman of the Department of Radiology at the University of California at San Francisco for 26 years. He is one of the world's most recognized radiologists and is currently Clinical Professor of Radiology at Cornell University in New York City. Dr. Margulis is a member of the IOM and has expertise in all imaging modalities and hospital/medical center administration as well as biologic applications of NMR.

Joseph F. Sackett, M.D.
Joseph F. Sackett, M.D. practiced the subspecialty of Neuroradiology and served as Chairman of the Department of Radiology at the University of Wisconsin. His teaching and research interests include: spine imaging, water soluble myelography, CT and MRI of brain and spine. The Department developed Digital Subtraction Angiography while he was chief of the section of Neuroradiology. He served and led many national organizations. His career was at the University of Wisconsin where he served as Department Chair for 15 years. The Department of Radiology grew in clinical service, research funding, and teaching innovation during his tenure. He published 76 articles, one textbook, 15 invited chapters and gave 131 invited lectures. As Trustee of the American Board of Radiology, Dr. Sackett introduced electronic imaging as a testing tool in Neuroradiology and developed the Certification of Added Qualification in Neuroradiology. Community service includes, Rotary Club, Tulane Medical Alumni Association, United States Power Squadron. Dr. Sackett retired from the faculty at the University of Wisconsin in 1997.

Anthony Sun, Ph.D., M.D.
Dr. Sun serves as a Principal of the Perseus-Soros BioPharmaceutical Fund (PSBF). Previously, Dr. Sun was an entrepreneur co-founding a disease management company for patients on blood thinners. In addition, Dr. Sun was an Adjunct Instructor of Medicine at the Hospital of the University of Pennsylvania where he provided consulting services to a large managed care organization and investigated pharmacoeconomic issues at the Leonard Davis Institute. Dr. Sun's background also includes basic science research at the N.I.H. on calcium ion channels and medical informatics studies at Albert Einstein Hospital on clinical information systems in the operating room. Dr. Sun received a B.S. in Electrical Engineering from Cornell University and an M.D. from Temple University School of Medicine with A.O.A. honors. In addition, he is a Board Certified Internist and has an M.B.A. from The Wharton School at the University of Pennsylvania.

Po Chi Wu, Ph.D.
Po Chi Wu is one of the Managing Directors of Alameda Capital, a newly established venture firm. Alameda Capital is currently raising a venture fund from investors in Asia and the US. Before this, he was president and co-founder of Allegro Capital, which manages Strategic Value 1, L.P., a fund that invests in high-technology companies based in the US. Dr. Wu has been involved with several non-profit organizations as a Director and former President of the Chinese Software Professionals Association (Silicon Valley), a trustee of the Asian Art Museum of San Francisco Foundation and Chair of the Technology Committee and a member of the Advisory Board of the Institute for Genetic Medicine at the University of Southern California. He is currently on the Advisory Council of the Lawrence Hall of Science at the University of California at Berkley. Po Chi Wu received his undergraduate degree in mathematics and music at the University of

California, Berkeley before going on to receive a doctorate in Molecular Biology at Princeton University.

James D. Cox, M.D.
Dr. Cox is Head of the Division of Radiation Oncology, Chair of the Department of Radiation Oncology, and he holds the Hubert L. and Olive Stringer Distinguished Chair in Oncology in Honor of Sue Gribble Stringer, at The University of Texas M. D. Anderson Cancer Center, Houston, Texas. He earned his medical degree with honors from the University of Rochester School of Medicine and Dentistry. He was a fellow for one year in the Department of Radiotherapy at the Gustave Roussy Institute in Villejuif, France. Dr. Cox was the first Chair of the new Department of Radiation Oncology at Columbia University College of Physicians and Surgeons and Director of Radiation Oncology at the Presbyterian Hospital in the City of New York. In 1988, he became Professor of Radiotherapy and Physician-in-Chief at The University of Texas M. D. Anderson Cancer Center in Houston, a position he held until 1992. Since 1995, he has served as Head of the Division of Radiation Oncology at M. D. Anderson. From 1987 to 1991, he was a member of the Board of Scientific Counselors of the Division of Cancer Treatment, the National Cancer Institute. From 1990 to 1993, he was the elected chair of the Committee of Cooperative Group Chairs of the Cancer Therapy Evaluation Program, Division of Cancer Treatment, National Cancer Institute. He is Editor-in-Chief of the International Journal of Radiation Oncology, Biology and Physics.

Albert O. Edwards, M.D.
Dr. Edwards is an assistant professor in the Department of Opthalmology at the McDermott Center for Human Growth and Development. He received a B.S. degree from the University of Houston, and an M.D./Ph.D. from Baylor College of Medicine. Dr. Edwards joined UT Southwestern Medical Center Chicago, after a fellowship in ophthalmic genetics and vitreoretinal surgery at the Oregon Health Sciences University, preceeded by a residency in opthalmology at the University of Illinois, Chicago. Dr. Edwards research explores the molecular genetics of macular degeneration and vitreoretinal dystrophies and has published extensively in these fields. He is a member of numerous learned societies, including the American Academy of Ophthamology and was a recipient of a Foundation Fighting Blindness Career Development Award, 2000-2003. He is listed in the Consumers Research Council of America's 2004 Guide to America's Top Ophthalmologists.

Robert E. Fischell, Ph.D.
Dr. Fischell is chairman and president of Fischell Biomedical, one of several companies he formed to develop and refine medical devices and systems. Fischell received a BS degree in mechanical engineering from Duke University, and an MS and honorary Doctor of Science degree from the University of Maryland. Fischell began his 38 year career at John Hopkins University Applied Physics Laboratory (APL) where he became the Chief Engineer of the Space Department. A prolific inventor with nearly 200 U.S. and international patents in his name, his work has resulted in a large variety of medical device improvements and new technologies including the first implantable insulin pump, the rechargeable pacemaker, and highly flexible stents for placement in coronary arteries. He is also the co-inventor of a microminiaturized computer that can be implemented in the human cranial bone to sense a precursor of an epileptic seizure and prevent it from

occurring. Fischell is a member of the Space Technology Hall of Fame. The University of Maryland presented him with the Outstanding Alumnus Award in 2000, and the 2001 Major F. Riddick, Jr. Entrepreneurship Award. Fischell serves as a director of the University of Maryland Foundation, and on the University's Board of Trustees and the Clark School of Engineering Board of Visitors. He is also a member of the National Academy of Engineering.